DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

3236 5 AUG 18 P2:20

JUL 19 2005

Mr. Ronald G. Sturtz
Founder
Lidtke Technologies Corporation
3202 S. Fair Lane
Tempe, Arizona 85282

Dear Mr. Sturtz:

This is in response to your letter of June 10, 2005 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Lidtke Technologies Corp. is making the following claims, among others, for the product **GlucoStat™**:

> "[F]or the lowering of peak postprandial blood glucose levels...lowering cholesterol, triglycerides...."
> "[C]onsumption of one capsule before each meal has resulted in very significant reduction in glucose...cholesterol, triglycerides...."

In the preamble to the January 6, 2000 final rule on structure/function claims (see 65 FR 1000 at 1018), FDA stated that claims about the maintenance of normal cholesterol levels did not necessarily constitute implied disease claims. We stated, however, that because "many people think of cholesterol solely in terms of the negative role of elevated cholesterol in heart disease," in order to avoid implying that the product prevents or treats heart disease, a cholesterol maintenance claim would have to clarify that the product is only for maintenance of cholesterol levels that are already within the normal range. The same principle applies to claims about the control of blood glucose levels; that is, a claim that does not establish that the claims are about blood glucose levels that are already within normal limits implies that the product is intended to treat elevated blood glucose (diabetes), which is a disease. The agency further stated in the preamble to the final rule that claims about lowering blood cholesterol would be treated as disease claims. Therefore, because the claims you are making for this product represent that the product is intended to affect blood glucose and blood cholesterol but do not also include a statement about them being intended to affect blood glucose and blood cholesterol that are already in the normal ranges, they are implied disease claims.

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21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for this product suggest that it is intended to treat, prevent, or mitigate diseases, such as diabetes and other disorders of blood glucose regulation and hypercholesterolemia. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, Montrose Metro II, 11919 Rockville Pike, Rockville, Maryland 20852.

Please contact us if we may be of further assistance.

Sincerely yours,

for Robert J. Moore

Susan J. Walker, M.D.
Director
Division of Dietary Supplement Programs
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Copies:
FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-310
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200
FDA, Los Angeles District Office, Office of Compliance, HFR-PA240

LIDTKE
TECHNOLOGIES

professional products from FINE BIOS NUTRIENTS

June 10, 2005

Food and Drug Administration
Office of Nutritional Products,
Labeling and Dietary Supplements (HFS-810)
Center for Food Safety and Applied Nutrition
200 C Street, SW
Washington, DC 20204

Dear Sirs:

Notice is hereby given pursuant to the requirements of section 403(r)(6) (21 U.S.C. 343(r)(6)) of the Federal Food, Drug, and Cosmetic Act and in accordance with the requirements of 21 CFR 101.93, that Lidtke Technologies Corp., 3202 S. Fair Lane, Tempe, AZ 85282 intends to market a dietary supplement bearing the following statements on the label and/or in the labeling:

(text of claim) "Introducing a patented product designed as nutritional support for the lowering of peak postprandial blood glucose levels, the reduction of blood-urea nitrogen, and the lowering of cholesterol, triglycerides, and homocysteine levels. This product is a natural blend of nutrients, available in convenient capsule form, and is supported by three patents and one patent pending. In preliminary tests, the consumption of one capsule before each meal has resulted in a significant reduction in glucose, BUN, cholesterol, triglycerides, and homocysteine.

U.S. Patent 6,602,909
U.S. Patent 5,559,142
U.S. Patent 3,080,234"

GlucoStat ™ (name of supplement)

Lidtke Technologies Corp. (brand name)

The undersigned certifies that the information contained in this notice is complete and accurate and that Lidtke Technologies Corp. has substantiation that the statement is truthful and not misleading.

Yours truly,

Ronald G. Sturtz
Founder

2005-4090
ADMS

#1285

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